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#### **ATTACHMENT**

Attachment Number 2-1 21 CFR 1020.30(d)

**NOTE:** Attachments are currently not available electronically in this file. If you need a hard copy please contact:

Department of Health and Human Services Regulation and Licensure Public Health Assurance Division Consumer Health Services P.O. Box 95007 Lincoln, NE 68509 (402)471-0563 or e-mail elaine.nelson@hhss.state.ne.us

JULY 22, 2001

Excerpts from 180 NAC 2 for Veterinary Facilities
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180 NAC 2

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JULY 22, 2001 REGULATION AND LICENSURE 180 NAC 2

TITLE 180 CONTROL OF RADIATION

CHAPTER 2 REGISTRATION OF RADIATION GENERATION EQUIPMENT FACILITIES AND

**SERVICES** 

#### PE AND AUTHORITY

<u>2-001.01</u> 180 NAC 2 provides for the registration of radiation generating equipment facilities and for the registration of persons providing radiation generating equipment installation, servicing of radiation sources, radiation measurements and other services. The regulations are authorized by and implement the Nebraska Radiation Control Act, <u>Neb. Rev. Stat.</u> section 71-3501 to 71-3519.

<u>2-001.02</u> In addition to the requirements of 180 NAC 2, all registrants are subject to the applicable provisions of 180 NAC 1, 4, 5, 6, 8, 9, 10, 15, 16, 17, and 18.

#### 2-002 DEFINITIONS: For purposes of 180 NAC 2:

<u>Facility</u> means the location at which one or more devices or sources are installed and/or located within one building, vehicle, or under one roof and are under the same administrative control.

#### 2-003 EXEMPTIONS

 $\underline{\text{2-003.01}}$  Electronic equipment that produces radiation incidental to its operation for other purposes is exempt from the registration and notification requirements of this part, providing dose equivalent rate averaged over an area of 10 square centimeters does not exceed 0.5 mrem (5  $\mu$ Sv) per hour at 5 cm from any accessible surface of such equipment. The production, testing, or factory servicing of such equipment shall not be exempt.

<u>2-003.02</u> Radiation generating equipment while in transit or storage incident thereto are exempt from the requirements of 180 NAC 2.

2-003.03 Domestic television receivers are exempt from the requirements of 180 NAC 2.

## <u>2-004 APPLICATION FOR REGISTRATION OF RADIATION GENERATING EQUIPMENT FACILITIES</u>: Each person having a radiation generating equipment facility shall:

<u>2-004.01</u> Apply for registration of such facility with the Agency within thirty (30) days following the commencement of the operation of a radiation generating equipment facility. Application for registration shall be completed on form NRH-4 furnished by the Agency and shall contain all the information required by the form NRH-4 and accompanying instructions; and submit the appropriate fee as specified in 180 NAC 18.

<u>2-004.02</u> Designate on the application form an individual to be responsible for radiation protection.

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<u>2-004.03</u> Each registrant shall prohibit any person from furnishing radiation generating equipment servicing or services as described in 180 NAC 2-005.04 to his radiation generating equipment facility until such person provides evidence that he has been registered with the Agency as a provider of services in accordance with 180 NAC 2-005. A list of these registrants shall be available for distribution by the Agency.

#### 2-005 APPLICATION FOR REGISTRATION OF SERVICING AND SERVICES

<u>2-005.01</u> Each person who is engaged in the business of installing or offering to install radiation generating equipment or is engaged in the business of furnishing or offering to furnish radiation generating equipment servicing, radiation source servicing, radiation measurements, and/or other services in this State shall apply for registration of such services with the Agency within 30 days following January 1, 1974 or thereafter prior to furnishing or offering to furnish any such services.

<u>2-005.02</u> Application for registration shall be completed on form NRH-9 furnished by the Agency and shall contain all information required by the Agency as indicated on the forms and accompanying instructions; and

1. Submit the appropriate fee as specified in 180 NAC 18.

2-005.03 Each person applying for registration under 180 NAC 2 shall specify:

- 1. That he has read and understands the requirements of 180 NAC 2; and
- 2. The services for which he is applying for registration; and
- 3. The training and experience that qualify him to discharge the services for which he is applying for registration. (See 180 NAC 15); and
- 4. The type of measurement instrument to be used, frequency of calibration, and calibration source; and
- 5. The type of personnel dosimeters supplied, frequency of reading, and replacement or exchange schedule.

<u>2-005.04</u> For the purpose of 180 NAC 2-005, services may include but shall not be limited to:

- Installation and/or servicing of radiation generating equipment and associated radiation generating equipment components. Services shall include those adjustments and measurements necessary for proper operation of radiation generating equipment. (See 180 NAC 15-033);
- 2. Calibration of radiation generating equipment or radiation measurement instruments or devices (See qualified expert training and experience qualifications in See 180 NAC 15-013.03);
- Radiation protection or health physics consultations, radiation measurements, or surveys (See qualified expert training and experience qualifications in 180 NAC 15-013.03);
- 4. Personnel dosimetry services. (See 180 NAC 15-034); and
- 5. Operation of radiation generating equipment by an individual (180 NAC 16).

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180 NAC 2 JULY 22, 2001 REGULATION AND LICENSURE 2-005.05 No individual shall perform services which are not specifically stated for that

individual on the certificate of registration issued by the Agency.

#### 2-006 ISSUANCE OF CERTIFICATE OF REGISTRATION (NRH-4 AND/OR NRH-9)

2-006.01 Upon a determination that an applicant meets the requirements of the regulations. the agency shall issue a Certificate of Registration.

2-006.02 The Agency may incorporate in the Certificate of Registration at the time of registration or thereafter by rule, regulation or order, such additional requirements and conditions with respect to the registrant's receipt, possession, use and transfer of radiation generating equipment, radiation source servicing, radiation measurements and/or services it deems appropriate or necessary.

2-007 EXPIRATION OF CERTIFICATE OF REGISTRATION: Except as provided by 180 NAC 2-008.02, each certificate of registration shall expire annually on the anniversary of the date issued

#### 2-008 RENEWAL OF CERTIFICATE OF REGISTRATION

2-008.01 Application for renewal of Registration shall be filed in accordance with 180 NAC 2-004 or 180 NAC 2-005.

2-008.02 In any case in which a registration not less than 30 days prior to the expiration of his existing certificate of registration has filed an application in proper form for renewal, such existing certificate of registration shall not expire until the application status has been finally determined by the Agency.

<u>2-009 REPORT OF CHANGES:</u> The registrant shall notify the Agency in writing within thirty (30) days of any change which would render the information contained in the application for registration no longer accurate

2-010 APPROVAL NOT IMPLIED: No person, in any advertisement, shall refer to the fact that he or his facility is registered with the Agency pursuant to the provisions of 180 NAC 2-004 or 180 NAC 2-005, and no person shall state or imply that any activity under such registration has been approved by the Agency.

#### 2-011 ASSEMBLER AND/OR TRANSFER OBLIGATION<sup>1</sup>

2-011.01 Any person who sells, leases, transfers, lends, disposes, assembles, or installs radiation generating equipment in this State shall notify the Agency within 15 days of:

1. The name and address of persons who have received this equipment;

<sup>&</sup>lt;sup>1</sup>In the case of diagnostic x-ray systems which contain certified components, a copy of the assembler's report (Form FDA 2579) prepared in compliance with requirements of 21 CFR Chapter 1, Section 1020.30(d) attached hereto as pages 466-468, except the stricken text of Attachment Number 2-1 and incorporated herein by this reference, shall suffice in lieu of any other report by the assembler.

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- 2. The manufacturer, model, and serial number of each radiation generating equipment transferred; and
- 3. The date of transfer of each radiation generating equipment.

<u>2-011.02</u> No person shall make, sell, lease, transfer, lend, assemble, or install radiation generating equipment or the components used in connection with such equipment unless such components and equipment when properly placed in operation and used shall meet the requirements of 180 NAC 2.

#### 2-012 OUT-OF-STATE RADIATION GENERATING EQUIPMENT

<u>2-012.01</u> Whenever any radiation generating equipment which is registered in another state or by the federal government is to be brought into the State, for any temporary use, the person proposing to bring such equipment into the State shall give written notice to the Agency (at least 2 working days) before such equipment is to be used in the State. The notice shall include:

- 1. the type of radiation generating equipment;
- 2. the nature, duration, and scope of use; and
- 3. the exact location(s) where the radiation generating equipment is to be used; and
- 4. States in which this equipment is registered.

<u>2-012.02</u> If, for a specific case, the (two working-day) period would impose an undue hardship on the person, upon application to the Agency, permission to proceed sooner may be granted.

#### <u>2-012.03</u> The person referred to in 180 NAC 2-012 .01 shall:

- 1. Comply with all applicable regulations of the Agency;
- 2. Supply the Agency with such other information as the Agency may reasonably request; and
- 3. Not operate within the State on a temporary basis in excess of 180 calendar days per year.
- 4. Submit the appropriate fee as specified in 180 NAC 18.

# NEBRASKA HEALTH AND HUMAN SERVICES SYSTEM DEPARTMENT OF REGULATION AND LICENSURE DIVISION OF PUBLIC HEALTH ASSURANCE X-RAY PROGRAM

For Agency Use Only					
Regist. No.					
State	Co				
Priority	Fee Det. No				

### <u>APPLICATION FOR REGISTRATION OF RADIATION GENERATING EQUIPMENT</u>

Instructions: Type or Print except where indicated. Retain one copy for your files and submit original application to: Nebraska Dept. of Health and Human Services Regulation and Licensure, Division of Public Health Assurance, 301 Centennial Mall South, P O Box 95007, Lincoln, NE 68509-5007.

1.a	1.a Legal Name and Street address of Applicant (Institution, Firm, Person, etc.)							
	Applicant Name:	, , , , , , , , , , , , , , , , , , , ,						
	Address:							
	Address.							
	City, State Zip:							
	Telephone #:							
	FAX #:							
	eMail Address:							
1.b	Street address(es) at which Radiation	on Generating Equipment will be us	ed. (If o	different than 1.a)				
	(1) Permanent	Address:		<u> </u>				
	(1) Tormanone	, tudiooo.						
		Other Oheder Zing						
		City, State Zip:						
	(2) Temporary Job Sites Throughout Nebraska?			□ Yes □ No				
<u>2.</u>	Billing Information		3.	Person Responsible for Radiation Protection				
	Address(if different than 1.a):							
				Title:				
	Person to Contact:			Telephone #:				
	Telephone #:							
	To a Specific Contact of City	.0						
<u>4.</u>	Type of Practice (see Instruction She	et)						

Control I nufacturer	Model No.	Serial No.	Date Installed	Date Manufactured	Control Room #		
6. CERTIICATION							
		<del>-</del>					
ervices Regulation and Lic	ensure, Title 180, Regula	in Item 1.a., certify that this tions for Control of Radiatio	application is prep n and that all info	pare n conformity with t rmation contained here	he Nebraska ein, including		
	Applicant Name for	m Itam 1 2					
	<i>Аррисап</i> т	ш цет 1.а.					
ifying official authorized t	o act on	Date:			_		
r	Item must be a get this document on behavices Regulation and Lic true and correct to the be	Item must be coming this document on behalf of the applicant named rvices Regulation and Licensure, Title 180, Regulator and correct to the best of our knowledge.	Item must be completed by  In this document on behalf of the applicant named in Item 1.a., certify that this a  Prices Regulation and Licensure, Title 180, Regulations for Control of Radiatio  true and correct to the best of our knowledge.  Applicant Name from Item 1.a.	Item must be completed by application application of the applicant named in Item 1.a., certify that this application is prepriotices Regulation and Licensure, Title 180, Regulations for Control of Radiation and that all infortrue and correct to the best of our knowledge.  Applicant Name from Item 1.a.	Item must be completed by applicant.)  In this document on behalf of the applicant named in Item 1.a., certify that this application is prepare n conformity with the revices Regulation and Licensure, Title 180, Regulations for Control of Radiation and that all information contained here the true and correct to the best of our knowledge.  Applicant Name from Item 1.a.		

Effective	Form N uly 22,	

Print Name and Title of certifying official

FORM	NRH_4a	( Additional	Machines)
LOUNI	NN 11-44	t Audinonai	Machines

Effective Date July 22, 2001

#### 5a. <u>LIST ADDITIONAL MACHINES ON THIS SHEET</u>

List each Type	machine on a sep # Tubes	arate line. Control Manufacturer	Model No.	Serial No.	Date Installed	Date Manufactured	Control Room #

